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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/444,281	11/19/1999	JAN BURIAN	660081.411	8461

500 7590 03/08/2002

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EXAMINER	
SCHNIZER, HOLLY G	
ART UNIT	PAPER NUMBER
1653	17

DATE MAILED: 03/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY FILE COPY

Office Action Summary	Application No. 09/444,281	Applicant(s) BURIAN ET AL.	
	Examiner Holly Schnizer	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,12,13,15-20 and 29-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,2,4,12,13,15-20 and 29-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 November 1999* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *16* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Claims

1. The Amendment filed December 17, 2001 (Paper No. 15) has been entered. Claims 3, 5-11, and 14 have been cancelled. Claims 29-53 have been added. Therefore, Claims 1, 2, 4, 12, 13, 15-20, and 29-53 are pending.

Drawings

2. The drawings filed 11/19/99 are objected to for reasons cited on the Form PTO 948 attached hereto.

Declaration

3. The Declaration of Burian and Bartfeld under 37 CFR 1.131 filed December 17, 2001 (Paper No. 14) has been entered and considered. In the response (Paper No. 15, p. 9) to the rejection of Claims 5-7, 10, and 14 under 35 U.S.C. 102(a) as being anticipated by Zhang et al., Applicants submit that the Declaration with the attached Exhibit provides evidence that the compositions of matter and methods claimed in the present application were conceived prior to 1998; the date of the Zhang et al. reference. The Declaration and Exhibit have been considered. However, while the Exhibit appears to show constructs containing multiple copies of a cationic peptide separated by a spacer sequence, there is no indication or evidence that the spacer sequence is anionic. Thus, the constructs shown in the Exhibit do not appear to be the same as those presently claimed which include, specifically, an anionic spacer. Consequently,

the Exhibit does not appear to provide evidence that constructs including an anionic spacer, as presently claimed, were contemplated prior to 1998. However, it is noted that the rejection of the claims under 35 U.S.C. 102(a) has been withdrawn for the reasons set forth below.

Objections and Rejections Withdrawn

4. The objections of Claims 5, 10, and 14 are withdrawn in light of the cancellation of the claims.

5. The rejection of Claims 5, 6, 7, 10, 11, and 14 under 35 U.S.C. 112, second paragraph is withdrawn in light of the cancellation of the claims.

6. The rejection of Claims 1, 2, 4, 12, 13, 15, 16, 17, 18, and 20 under 35 U.S.C. 112, first paragraph for lack of enablement is withdrawn in light of the amendment to claim 1.

7. The rejection of Claims 5-7, 10, and 14 under 35 U.S.C. 102(a) as being anticipated by Zhang et al. (Biochem. Biophys. Res. Comm. (1998) 247: 674-680; Ref. AP of IDS of Paper No. 11) is withdrawn in light of the cancellation of these claims. Unlike the cancelled claims, new Claims 29-53 have the added limitation that the structure of the expression cassette be (carrier)[(cationic peptide)(anionic spacer peptide)]$_n$-(cationic peptide). The order of the individual components of the Zhang et al. cassettes is (carrier protein)-(anionic peptide)-(cleavage site)-(cationic peptide) (see construct no. 1 in Table 2) which is a different order than the cassettes of the claimed invention. Zhang et al. do not teach an expression construct with the structure of that of

the claimed invention. Zhang et al. describe the expression levels of a variety of expression cassettes (see p. 676, Table 2) and show that the identity/structure and position of each of the peptides relative to the other is critical to successful expression (see enablement rejection below). Therefore, since Zhang et al. only teach expression cassettes wherein the anionic peptide is N-terminal to the cationic peptide and since Zhang et al. teach that the order of the individual peptides is crucial to the success of expression, it appears that the Zhang et al. reference does not anticipate nor render obvious the presently claimed invention.

Rejections Maintained

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 29-53 are rejected under 35 U.S.C. 112, first paragraph. As stated in the previous Office Action (Paper No. 12), the specification is enabling for the following:

1) expression cassettes comprising the structure (cationic peptide)-[(cleavage site)-(cationic peptide)]n, wherein n has a value of 1-4 or

2) expression cassettes comprising the structures and encoding the peptides disclosed in the specification.

However, the specification does not reasonably provide enablement for

1) expression cassettes comprising the structure (cationic peptide)-[(cleavage site)-cationic peptide)]$_n$ wherein n is between 1 and 100 (clm 1), 5 and 40 (clm 3) or

wherein the fusion protein comprises from 4 to 40 (clm 8) or 3 to 15 (clm 9) cationic peptides, or

2) for expression cassettes comprising the structure (cationic peptide)-[(cleavage site)-cationic peptide)]$_n$ wherein n is between 1 and 100 and wherein the nucleic acid also encodes a carrier protein at the C-terminus (clm 2) or

3) an expression cassette wherein the nucleic acid encodes a fusion protein comprising a carrier protein, an anionic spacer with the structure (cleavage site)-(anionic spacer peptide), and a cationic peptide with the structure (cleavage site)-(cationic peptide) the carrier protein, the anionic spacer, and the cationic peptide can be in any order. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

10. Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d, 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). These factors include (1) quantity of experimentation, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

11. Applicants argue that the mere fact that exemplified embodiments in the specification are more limited than those recited in the claims does not provide reason

for the examiner to hold the claims as non-enabled. This argument has been considered but is not deemed to be persuasive for the following reason:

12. Applicants are not required to exemplify all embodiments of the invention that are encompassed by the claims *in instances wherein one of skill in the art could use the information in the specification as guidance to practice the other embodiments with a reasonable expectation of success*. However, in the present case, it appears that one of skill in the art would not know how to practice the invention commensurate in scope with the claims without undue experimentation for the reasons set forth in the Office Action of Paper No. 12 and repeated below. In the previous Office Action (p. 7-10 of Paper No. 15), the examiner provided evidence that the state of the art at the time of the invention was such that specific sequences of the fusion partners and their positioning relative to each other and the peptide were crucial to the success of using the expression cassettes in expressing cationic peptides and that the design of expression cassettes that can be used successfully is highly unpredictable. The response filed December 17, 2001 (Paper No. 15) does not address or dispute this evidence.

13. As stated in the previous Office Action:

14. Disclosed order and relative number of components of expression cassette required.

15. New claims 29, 33, 37, 38, and 40 (which are drawn to the same expression cassettes as previously rejected and now cancelled claims 5-7, 10, 11, and 14, respectively) are drawn to expression cassettes encoding fusion proteins with carrier proteins, anionic spacers, and cleavage sites yet the claims indicate that the number

and positions of any of these components is almost unlimited. The new claims have been slightly narrowed such that the cassette must have a core structure as follows: (carrier peptide)-[(cationic peptide)-(anionic peptide)]$_n$-(cationic peptide). However, there is no limit as to the number or positions of carrier peptides, anionic peptides or cationic peptides outside of that structure. Furhtermore, there is no limit as to the identity/sequence of the carrier proteins, anionic peptide or cationic peptide within the structure. However, the art shows that the sequence and position of each component is an essential element to the success of using the expression cassettes in expressing cationic peptides. Zhang et al. state that, "specific sequences of the fusion partner and their positioning relative to each other and the peptide were crucial" (p. 678, Col. 2, lines 10-13). For example, Zhang et al. show that the anionic domain must be immediately upstream of the cationic domain (p. 678, Col. 2, lines 16-17; and Table 2). Zhang et al. do not provide any guidance as to why the order is important therefore, the construction of the expression cassettes that can be used successfully to produce cationic peptides appears to be unpredictable. The specification only provides guidance as to the success in using multidomain constructs wherein the cationic peptide is an indolicidin sequence, the carrier protein is a cellulose binding domain (the carrier protein), the anionic spacer peptide has the sequence of HEAEPEAEPIM(SEQ ID NO:27) and wherein these components are placed in a particular order: *(carrier)* -[(cationic peptide)-(anionic peptide)]$_n$-(cationic peptide)$_2$, wherein n=1-28 (cationic repeats=3-30), or *carrier*-[(cationic peptide)-(anionic peptide)]$_n$, wherein n=5, 10, and 15 (presence of a carrier does not appear to be required for successful expression). The specification

does not provide any guidance as to whether any of the components can be placed at any other position and still achieve successful expression. Therefore, in light of Zhang et al. showing that the order of components is critical to the success of using the expression cassettes, the unpredictability of what order or what combination of components would produce a successful expression cassette, and in light of the absence of any guidance in the specification as to the success of using expression cassettes other than those disclosed in the specification, it would require undue experimentation to successfully use expression cassettes containing components other than those disclosed in the specification and in the positioning disclosed in the specification.

16. New Claims 30-32, 34-36, 39, and 41-53 are added to this rejection for the reasons cited above. New Claims 30-32, 34-36, 39, and 41-46 only add limitations as to the location and identity or structure of individual components of the cassette (clms 30-32, 34-36, 43, 44, 45, 46); and as to the number of cationic peptides are present in the cassette (clms. 39, 41, and 42). These limitations do not proved the structure of the anionic spacer peptide or the particular order of the individual components that would allow for successful practice of the invention for the reasons cited in the previous Office Action and above (see underlined above). Claims 47-53 are drawn to recombinant host cells containing the expression cassettes and methods of producing fusion proteins using the expression cassettes and contain the limitations of the claims from which they depend. Therefore, Claims 47-53 are rejected for the reasons set forth above and in the previous Office action.

17. Due to the large quantity of experimentation necessary to generate the infinite number of expression cassettes recited in the claims and possibly screen same for successful expression, the lack of direction/guidance presented in the specification regarding which structural features are required in order to achieve successful expression, the absence of working examples directed to cassettes other than those of the structures disclosed, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of placement of different components in different positions in an expression construct, and the breadth of the claims which fail to recite any structural limitations, undue experimentation would be required of the skilled artisan to use the claimed invention in its full scope. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner. Such a contribution would involve the determination of what structural features of an expression cassette expressing a cationic peptide are essential for successful expression of the cationic peptide. It is this additional characterization of the protein that is required in order to obtain the functional and structural data needed to permit one to produce a protein that meets both the structural and functional requirements of the instant claims that constitutes undue experimentation.

New Rejections

The following new rejections were necessitated by amendment (new claims) or by new information provided in the IDS filed after the first Office action (Paper No. 16) with a fee set forth in 37 CFR 1.17(p).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-53 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

New Claim 29 is indefinite because the claim is unclear as to the metes and bounds of the position of the cleavage site between the cationic peptide and the carrier. There is lack of antecedent basis for "the cationic peptide" since there are more than one cationic peptides encoded within the cassette. Therefore, the claim is confusing as to which of the cationic peptides is being referred. Is the cleavage site intended to be between the carrier protein and the adjacent cationic peptide (the first cationic peptide of the (cationic peptide)-(anionic peptide) repeat)? Or, is the cleavage site intended to be anywhere between the carrier peptide and the antimicrobial cationic peptide? Claims 30-53 are also rejected since they depend from Claim 29 but do not correct its deficiencies.

Claim 33 fails to further limit Claim 29 from which it depends. A dependent claim has each and every limitation of the Claim from which it depends. Since Claim 29 is

limited to the following structure, (carrier amino acid sequence)-[(cationic peptide)-(anionic spacer peptide)]$_n$ –(cationic peptide), Claim 29 and thus dependent claim 33 are limited to a cassette wherein the carrier is located at the N-terminus of the fusion protein. Therefore, the limitation of Claim 33, that the carrier is located at the N-terminus of the fusion protein fails to further limit Claim 29. Correction is required. Claims 47-50 and 53 are also rejected since they ultimately depend from Claim 33 but do not correct its deficiencies.

Claim 34 is confusing as to how "the carrier" can be located at the C-terminus of the fusion protein when Claim 29, from which Claim 34 depends, indicates that "the carrier" is located at the N-terminus (see line 8 of Claim 29). Is "the carrier" located at the C-terminus an additional carrier peptide to the one located at the N-terminus? If so, then "the carrier" lacks antecedent basis. Clarification of the claim is required. Claims 47-50 and 53 are also rejected since they ultimately depend from Claim 34 but do not correct its deficiencies.

Claim 44 is rejected because it lacks a sequence identifier. Where a claim discusses a sequence greater than 4 amino acids in length, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the claim, even if the sequence is also embedded in the text of the claims (see MPEP 2421.01, MPEP 2422 and 37 CFR 1.821 cited therein). Correction is required. Claims 47-50 and 53 are also rejected since they ultimately depend from Claim 44 but do not correct its deficiencies.

Claim 46 is unclear as to what is meant by "the cleavage site is with the...". What does it mean that the cleavage site "is with" the carrier amino acid sequence, etc. Likewise, what does it mean that the cleavage site "is with" a combination of, for example, a carrier amino acid sequence and an anionic spacer peptide? Clarification is required. Claims 47-50 and 53 are also rejected since they ultimately depend from Claim 46 but do not correct its deficiencies.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1, 2, 4, 16, 17, 18, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Better (U. S. Patent No. 5,851,802; reference AB in IDS of Paper No. 16).

Better discloses a multi-domain fusion protein expression cassette, comprising a promoter operably linked to a nucleic acid molecule which is expressed as an insoluble protein (see Col. 22, line 55), wherein the nucleic acid molecule encodes a polypeptide comprising the structure (cationic peptide)[(cleavage site)-(cationic peptide)]$_n$ wherein n has a value of up to 4 (see Fig. 5 and Col. 8, lines 43-45 showing up to 5 peptide repeat

units). Better teaches that the highest yield of product comes from a vector containing an expression cassette with four cationic peptide repeat units (Col. 8, lines 43-45 and Fig. 5). Better indicates that the preferred structure of the cassettes contains a carrier protein as exemplified by 5'-(nucleic acid molecule encoding carrier)-(cleavage site)-(nucleic acid molecule encoding at least one cationic peptide)-3' (see Col. 7, lines 58-67) and that the carrier peptide may also be a cationic peptide (Col. 8, line 7-10). Better teaches that the cleavage sites may be cleaved by acid hydrolysis (low pH)(Col. 20, lines 22-23). The examples of Better teach that the disclosed vectors containing the expression cassettes can be transformed into *E. coli* cells in a method of expressing of the fusion proteins that contain the cationic peptides (See Example 2, Col. 16 and Example 3). The cationic peptide in the expression cassettes disclosed in Better is the antimicrobial BPI peptide (see Col. 7). Thus, it appears that Claims 1, 2, 4, 16, 17, 18, and 20 are anticipated by Better.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Better (ref. AB of IDS of Paper No. 16) in view of Zhang et al. (Biochem. Biophys. Res. Comm. (1998) 247: 674-680; Ref. AP of IDS of Paper No. 11).

19. Better discloses a multi-domain fusion protein expression cassette, comprising a promoter operably linked to a nucleic acid molecule which is expressed as an insoluble protein (see Col. 22, line 55), wherein the nucleic acid molecule encodes a polypeptide comprising the structure (cationic peptide)[(cleavage site)-(cationic peptide)]$_n$ wherein n has a value of up to 4 (see Fig. 5 and Col. 8, lines 43-45 showing up to 5 peptide repeat units). Better teaches that the highest yield of product comes from a vector containing an expression cassette with four cationic peptide repeat units (Col. 8, lines 43-45 and Fig. 5). Better indicates that the preferred structure of the cassettes contains a carrier protein as exemplified by 5'-(nucleic acid molecule encoding carrier)-(cleavage site)-(nucleic acid molecule encoding at least one cationic peptide)-3' (see Col. 7, lines 58-67) and that the carrier peptide may also be a cationic peptide (Col. 8, line 7-10).

20. Better does not teach that the expression cassette has one of the promoters claimed in Claim 15.

Zhang et al. teach a multidomain fusion protein expression cassette, comprising a T7 promoter (see p. 678, Col. 2, 4th paragraph).

Better and Zhang et al. are both concerned with the high level expression of antimicrobial cationic peptides as repeats in fusion proteins. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention, to modify the expression vectors of Better to include the T7 promoter since Zhang et al. teach that the T7 promoter is a strong endogenous promoter and since Zhang et al. show that expression levels of their fusion proteins increased when the vectors were modified to contain the T7 promoter (see p. 678, Col. 2, paragraph 4).

Conclusions

No Claims are allowable.

With respect to the new prior art rejection, Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on November 21, 2001 (Paper No. 16) prompted the new ground(s) of rejection presented in this Office action. With respect to the rejection of the new claims, Applicant's amendment (new claims) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 609(B)(2)(ii) for final rejection based on IDS and MPEP § 706.07(a) for final rejection necessitated by amendment. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-3722. The examiner can normally be reached on Mon. & Thurs., 8am-5:30pm and Tues. & Wed. 9-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703 308-0196.

Holly Schnizer
March 8, 2002

CHRISTOPHER S. F. LOW
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